

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-0413V

Filed: January 31, 2019

UNPUBLISHED

TERESA TINLEY,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

Special Processing Unit (SPU);
Ruling on Entitlement; Decision After
Fact Hearing and Fact Ruling; Onset;
Table Injury; Influenza (Flu) Vaccine;
Shoulder Injury Related to Vaccine
Administration (SIRVA)

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for petitioner.

Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT¹

Dorsey, Chief Special Master:

On March 23, 2017, Teresa Tinley (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*,² (the “Vaccine Act”). Petitioner alleges that she suffered left shoulder injuries caused by an October 30, 2015 influenza (“flu”) vaccination. Petition at 1-2. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons discussed below, the undersigned finds that petitioner is entitled to compensation.

¹ The undersigned intends to post this ruling on the United States Court of Federal Claims' website. **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access. Because this unpublished ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services).

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

a. From Petition Filing to Fact Hearing

On March 23, 2017, Ms. Tinley filed her petition (ECF No. 1). On March 28, 2017, she filed medical records marked as Exhibits 1-8 (ECF Nos. 6 and 7). She also filed a Statement of Completion on March 28, 2017 (ECF No. 9). The initial status conference was held on May 2, 2017 (ECF No. 11). Additional medical records were filed as Exhibit 9 on June 7, 2017 (ECF No. 12).

On October 3, 2017, respondent filed a status report requesting additional medical records (ECF No. 18). On November 15, 2017, petitioner filed additional medical records as Exhibits 10 and 11 (ECF No. 21). On December 15, 2017, respondent submitted a status report requesting 45 days to file a Rule 4(c) Report (ECF No. 25). This request was granted.

On January 29, 2018, respondent filed his Rule 4(c) Report (ECF No. 30). Respondent argued that the medical records “fail[ed] to establish by preponderant evidence that the vaccine administration caused petitioner to suffer SIRVA. Petitioner did not complain of shoulder pain to a medical provider until March 22, 2016, approximately five months after vaccination . . . She did not receive any evaluation or treatment of her alleged arm pain until a few weeks later, on April 6, 2016. Therefore, it is not clear that petitioner’s pain began within forty-eight hours of vaccination.” Respondent’s Rule 4(c) Report at 3-4 (ECF No. 30).

Thereafter, following a status conference held by the staff attorney managing this case, the undersigned requested that petitioner inform the court how she wished to proceed in this case (ECF No. 31). On March 16, 2018, petitioner filed a status report indicating that she wished to proceed with a hearing (ECF No. 32). A fact hearing was scheduled, and petitioner was afforded the opportunity to file additional evidence in the form of an affidavit from her sister (ECF Nos. 33, 34, 36). Petitioner later reported that she would not be submitting an affidavit from her sister. Petitioner’s Status Report, filed May 22, 2018 (ECF No. 38).

b. Fact Hearing and Ruling

A fact hearing was held in Washington, D.C., on July 17, 2018. Ms. Tinley was the sole witness and she appeared via video-conference from Pennsylvania with her attorney. At the conclusion of the hearing, the undersigned informed the parties that she intended to issue a ruling from the bench. The undersigned then issued a bench ruling finding that the onset of petitioner’s symptoms occurred within 48 hours of vaccination.

On September 5, 2018, the undersigned issued a written fact ruling memorializing the bench ruling. Fact Ruling, issued Sept. 5, 2018 (ECF No. 46). In the

fact ruling, the undersigned found that the onset of petitioner's left shoulder injuries occurred within 48 hours of her October 30, 2015 influenza vaccination.

On August 31, 2018, the undersigned issued a scheduling order directing the parties to file any additional evidence they wished to have considered concerning entitlement by October 5, 2018. The parties were informed that after that date, the record concerning entitlement would close and a ruling on entitlement would issue.

II. Factual History

Ms. Tinley was 65 years old when she received the flu vaccine in her left arm at a Rite Aid pharmacy on October 30, 2015. Petitioner's Exhibit ("Pet. Ex.") 1 at 1-2. She was in good health and had no prior history of pain or injury in either shoulder. See Tr. at 6-7; see *generally* Pet. Ex. 7 at ¶¶ 1, 9-10, 15-16. Petitioner averred in her affidavit that the injection "immediately hurt," and that the pharmacist told her it would be sore for a couple of days. *Id.* at ¶ 4. Petitioner averred that the pain worsened in November 2015 and by January 2016 the range of motion in her left shoulder had declined. *Id.* at ¶¶ 6-7. During this time, she used ice packs throughout the day. *Id.* She averred that in February 2016, she was still in pain and realized it was not going to go away on its own. *Id.* at ¶ 8.

On March 22, 2016, petitioner returned to Rite Aid to seek advice. *Id.* at ¶ 9. A Vaccine Adverse Event Reporting System ("VAERS") report was filed in petitioner's name by Tim Lisberg of Rite Aid. Pet. Ex. 6. The VAERS report stated that petitioner had "pain in upper arm, 'debilitating' according to patient. Pain still present as of 3/22/16, when vaccine given 10/30/15." *Id.* at 1. The VAERS report listed the date of vaccination as 10/30/15 and the date of adverse event onset as 10/31/15. *Id.* Petitioner testified that the report was filed by Rite Aid after she returned there in March 2016 reporting her symptoms. Tr. at 19. She testified that initially she went to Rite Aid rather than a doctor "[t]o ask for advice. I thought this is where it started, maybe they can direct me, maybe they can tell me what I need to do or tell me if this has happened before to others . . . just to get advice." *Id.* Petitioner testified that at Rite Aid she was told her a VAERS report would be filed and she was informed of the Vaccine Program.

On April 6, 2016, petitioner reported to orthopedist Jane Tan, M.D. Pet. Ex. 3 at 1. Petitioner reported that she had a flu shot in October 2015 and afterward had swelling and redness. *Id.* She reported that since then she had difficulty with overhead reaching and dropping objects. *Id.* On examination, she exhibited positive Neer's and Hawkins impingement signs and tenderness over the bicipital groove. *Id.* Her left arm demonstrated reduced external rotation of 45°, compared to 60° on her uninjured right side. *Id.* X-rays were taken and found to be normal. *Id.* Dr. Tan diagnosed petitioner with left rotator cuff syndrome and left biceps tendinitis and administered a cortisone injection to the left subacromial space. *Id.* at 1-2. Dr. Tan provided petitioner with a physical therapy prescription for use as needed. *Id.* at 2.

On May 25, 2016, petitioner was seen by nurse practitioner (“NP”) Karen Richard-Reynolds at Eagles Landing Family Practice. Petitioner reported that she received a flu shot at Rite Aid in October 2015 and had “severe and constant” pain in her left arm. Pet. Ex. 2 at 1. NP Richard-Reynolds diagnosed petitioner with left upper arm pain and provided her with a physical therapy referral. *Id.* at 2.

On June 1, 2016, petitioner reported to physical therapist Stevi Wheeler of Benchmark Physical Therapy for an initial evaluation. Pet. Ex. 4 at 15. Petitioner reported that she received a flu shot in her left arm and felt something rip in her arm. *Id.* Petitioner reported that she had been “very inhibited” for several months, and had ‘dealt with it’ for several months until April when she went to see an orthopedist and received a steroid injection with no changes. *Id.* Petitioner reported moderate to severe loss of function, severe stiffness, pain, and weakness, and moderate to severe problems with driving. *Id.* On examination, physical therapist Wheeler found that petitioner’s active range of motion was limited to 85° in flexion and 70° in abduction and stated a goal of 180° for both. *Id.* at 16.³

On June 2, 2016, petitioner reported to physical therapist Wheeler for a second physical therapy session. *Id.* at 13. Petitioner reported a pain level of 5/10 and that her arm was better but remained sore when trying to sleep. *Id.* On June 6, 2016, petitioner returned for another physical therapy session. She reported a pain level of 5/10 and reported that her pain was better and she had not had an episode of pain reaching 10/10 recently. *Id.* On June 8, 2016, petitioner attended a fourth physical therapy session. *Id.* at 7. She reported a pain level of 5 out of 10 and that she was slowly getting better. *Id.* On June 30, 2016, after four sessions, petitioner was discharged from physical therapy at her request for financial reasons. Pet. Ex. 4 at 4-6.

On June 9, 2016, petitioner was seen by physician assistant (“PA”) Miranda Stone at Eagles Landing Family Practice. Pet. Ex. 2 at 4. Petitioner reported pain in her left arm for the past eight months following a flu vaccination on 10/30/15. *Id.* Petitioner reported that she believed she was injected in a nerve and had experienced sharp and stabbing pain with constant throbbing. *Id.* Petitioner reported that she had started physical therapy but that the pain had not resolved. *Id.* PA Stone diagnosed petitioner with left shoulder strain, directed petitioner to stop physical therapy for two weeks, and referred her for an orthopedic consultation.

Ms. Tinley filed an affidavit dated February 8, 2017 in which she averred that prior to the October 30, 2015 vaccination, she was in “good health,” walked three miles a day, did water aerobics. Pet. Ex. 7 at ¶ 1. She averred that the flu vaccine administered on October 30, 2015 “immediately hurt.” *Id.* at ¶ 4. She stated that the

³ The record states, “Right AROM [Active Range of Motion].” Pet. Ex. 4 at 16. However, the reference to the right shoulder appears to be a typo. The rest of physical therapist Wheeler’s initial evaluation record indicates that the evaluation concerned petitioner’s left shoulder. See, e.g., “TTP [tender to palpation] along L upper arm,” Pet. Ex. 4 at 16, “Patient presents with signs and symptoms that are consistent with: L arm pain,” *Id.* at 17, diagnosis of “M79.622 Pain in left arm, M 25.512 Pain in left shoulder.” *Id.* at 15.

morning after the vaccine administration, the injection site “was puffy and more red than the previous day. The area was very sore to the touch.” *Id.* at ¶ 5. She averred that in November 2015, “the pain in my left arm at the injection site increased to a throbbing pain It became difficult to sleep Due to the pain that accompanied trying to find a comfortable position to sleep, I was up and down throughout the night.” *Id.* at ¶ 6. By January 2016, she averred, “the range of motion of my left arm declined. If I moved my arm towards my backside or tried to raise it over my head to put on clothes, I had excruciating pain. It was as if a knife were stabbing into my flesh.” *Id.* at ¶ 7.

Petitioner further averred that since her flu vaccination, “I am unable to use my left arm to dress myself. I cannot use my left arm to help wash my back or lift it high enough to wash my hair Simply opening or closing my car door, or latching a seatbelt with my left arm leads to severe pain. As a whole, I have had to adjust my daily routine in order to avoid the excruciating pain My entire life changed after the flu vaccine.” *Id.* at ¶¶ 15-16.

At the hearing, petitioner testified about her pre-vaccination health status. She testified that before the vaccination she never had problems with either shoulder. Transcript (“Tr.”), Fact Hearing (July 17, 2018), at 7. She further testified that prior to her vaccination:

I was a very healthy person. I never had any injuries, [took] no medications, very self-sufficient, very independent woman. I cut grass, four acres of grass every weekend, cut tree limbs down, cleaned my house, did interior decorating for people, previously had worked in the construction industry . . . did water aerobics, exercising, walking two, three miles a day, sometimes twice a day, just very active.

Tr. at 6-7.

Petitioner testified that she “experienced pain immediately [after vaccination] it’s still sore right here.” Tr. at 12. She testified that at the time of vaccination she had “no insurance other than Medicare” and her sole sources of income were Social Security and income from a seasonal job where she formerly worked for approximately three to five months per year. *Id.* at 15-16. She explained that she considered going to the emergency room due to her shoulder pain but “[o]nly having Medicare, I knew that I would have to pay at least 20 percent copay and it was the money factor.” *Id.* at 20. For this reason, she opted to see an orthopedic specialist rather than going to the emergency room. *Id.*

She testified that the “cortisone shot [administered by orthopedist Dr. Tan] really didn’t do anything that I could tell.” *Id.* at 22. She explained that after four physical therapy sessions and two primary care visits, she had ceased seeking formal treatment for her shoulder because “[n]o one seemed to understand about the pain [a]nd they wanted to mask it with pain pills I did not want to take pain pills. I was wanting to know what was wrong and what we could do to make it better, and they could not

give me that answer.” *Id.* at 23. She explained that physical therapy had helped some, but she stopped going because she ran out of money for copays and felt the last visit may have reinjured her shoulder. *Id.*

Ms. Tinley filed an affidavit dated August 16, 2016 averring that “no civil actions have been filed, nor have I received or collected an award or settlement of a civil action for damages for this vaccine related injury. Furthermore, I am not aware of anyone who has received or collected an award or settlement of a civil action for damages for this vaccine related injury.” Pet. Ex. 8 at 1.

III. Respondent’s Rule 4(c) Report

On January 29, 2018, respondent filed his Rule 4(c) Report (ECF No. 30). Respondent argued that the medical records “fail[ed] to establish by preponderant evidence that the vaccine administration caused petitioner to suffer SIRVA. Petitioner did not complain of shoulder pain to a medical provider until March 22, 2016, approximately five months after vaccination . . . She did not receive any evaluation or treatment of her alleged arm pain until a few weeks later, on April 6, 2016. Therefore, it is not clear that petitioner’s pain began within forty-eight hours of vaccination.” Respondent’s Rule 4(c) Report at 3-4 (ECF No. 30).

In the Rule 4(c) Report, respondent further asserted that a special master “cannot find that a vaccine-related injury occurred based solely upon the claims of petitioner (see 42 U.S.C. § 300aa-13(a)(1)); it must be substantiated by petitioner’s medical records, or by a credible expert medical opinion.” *Id.* at 4. Respondent argued that in this case “the physicians who evaluated petitioner for her shoulder pain noted the reported temporal association between the flu shot and the shoulder pain, but no physician opined that petitioner’s October 30, 2015, flu vaccination was the cause of her alleged injury.” *Id.*

IV. Legal Standard

Pursuant to Vaccine Act § 13(a), compensation shall be awarded if a special master finds on the record as a whole that the petitioner has “demonstrated by a preponderance of the evidence the matters required in the petition” by Vaccine Act § 11(c)(1). A petitioner can assert a Vaccine Injury Table (“Table”) petition under Vaccine Act § 11(c)(1) by filing an affidavit and supporting documentation demonstrating, *inter alia*, that the person who suffered an injury or died:

1. Received a vaccine set forth in the Table (Vaccine Act §11(c)(1)(A));
2. Received the vaccine in the United States (Vaccine Act §11(c)(1)(B));
3. Sustained, or had significantly aggravated any illness, disability, injury, or condition set forth in the Table, and the first symptom or manifestation of the onset or significant aggravation “occurred within the time period after vaccine administration set forth in the Vaccine Injury Table” (Vaccine Act §11(c)(1)(C));

4. Suffered the residual effects or complications of the injury for more than six months after the administration of the vaccine (Vaccine Act §11(c)(1)(D)); and
5. Has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death (Vaccine Act §11(c)(1)(E)).

In this case, the undersigned finds that petitioner has demonstrated by a preponderance of the evidence the matters required in the petition pursuant to §11(c)(1) of the Vaccine Act as listed above. Therefore, petitioner is entitled to compensation.

a. Petitioner received a vaccine set forth in the Table

Petitioner has demonstrated that on October 30, 2015, she received an influenza vaccination, which is a vaccine set forth in the Table. Therefore, this requirement is met.

b. Petitioner received the vaccine in the United States

The preponderance of the evidence demonstrates that petitioner received her flu vaccination at a Rite Aid in Covington, Georgia, which is in the United States.

c. Petitioner sustained an injury set forth in the Table, and the first symptom or manifestation of the onset occurred within the time set forth in the Table

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table ("Table"). See Vaccine Injury Table: Qualifications and Aids to interpretation. 42 C.F.R. § 100.3(c)(10). The undersigned determines that petitioner has demonstrated that her injury meets the SIRVA Table requirements, as informed by the Qualifications and Aids to Interpretation for SIRVA criteria. The criteria are as follows:

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

Id.; see also National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July

29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052).

i. This case was filed on or after March 21, 2017, the date the Table changes listing SIRVA took effect

The petition in this case was filed on March 23, 2017. The Table changes listing SIRVA as a Table injury took effect on March 21, 2017. Therefore, the Table changes apply to this petition and petitioner's claim may be analyzed as a Table SIRVA case. In addition, as explained further below, the undersigned finds that petitioner has demonstrated that her injury meets the Table SIRVA criteria.

ii. Petitioner had no history of pain, inflammation or dysfunction of her left shoulder prior to vaccine administration that would explain her signs, symptoms, and examination findings after vaccine injection

Respondent has not contested that petitioner meets this criterion, and the undersigned finds that she has demonstrated a lack of history of pain, inflammation, or dysfunction of her left shoulder that would explain her symptoms. Prior to vaccine administration, petitioner was a healthy, active adult. She rarely had the need to see a doctor and performed regular exercise and home and yard maintenance work. Therefore, petitioner has demonstrated by a preponderance of the evidence that she had no history of left shoulder injuries that would explain her post-vaccination symptoms.

iii. Petitioner's injury occurred within 48 hours, which is the specified time frame

Pursuant to Vaccine Act § 13(b)(2), a special master may find that the first symptom or manifestation of onset occurred within the time period set forth in the Table even if the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. In the September 5, 2018 fact ruling, the undersigned determined that the onset of petitioner's left shoulder injuries occurred within 48 hours of her October 30, 2015 influenza vaccination based on medical records and petitioner's testimony and affidavit. Fact Ruling, issued Sept. 5, 2018 (ECF No. 46). Thus, petitioner has demonstrated by a preponderance of the evidence that her injury occurred within the time specified in the Table for a SIRVA.

iv. Petitioner's pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered

Respondent has not contested that petitioner meets this criterion. Petitioner testified that her symptoms occurred in her left shoulder. The undersigned finds that

she has demonstrated that her pain and reduced range of motion were limited to the shoulder in which the intramuscular vaccine was administered.

v. No other condition or abnormality is present that would explain petitioner's symptoms

Respondent has not contested that petitioner meets this criterion, and the undersigned finds that the preponderance of the evidence supports a conclusion that there is no other condition or abnormality present that would explain petitioner's condition.

vi. Conclusion concerning Table SIRVA criteria

The undersigned concludes that petitioner has demonstrated that she meets all requirements to demonstrate entitlement to compensation for a SIRVA as included on the Table.

d. Petitioner suffered the residual effects or complications of the injury for more than six months

Petitioner continued physical therapy and medical evaluation until June 2016, approximately eight months following her vaccination. Thus, she has satisfied the requirement that she demonstrate that she suffered the residual effects of her injury for more than six months.

e. Petitioner has not previously collected an award or settlement of a civil action for damages

Petitioner filed an affidavit averring that she has not previously collected an award or settlement of a civil action for damages. Thus, this requirement is satisfied.

f. Respondent's other contentions

In his Rule 4(c) Report, respondent contends that pursuant to Vaccine Act § 13(a)(1), a special master cannot find a vaccine-related injury occurred based solely upon the claims of petitioner. Respondent's Rule 4(c) Report at 4. Respondent further argues that petitioner's physicians did not opine that her vaccination was the cause of her injury. The undersigned finds these arguments unavailing.

Section 13(a)(1) states that a special master cannot find a vaccine-related injury "based on the claims of a petitioner alone, *unsubstantiated by medical records or medical opinion*" (emphasis added). Therefore, such a finding cannot be made *solely* based on the claims of a petitioner, but it may be made based on a petitioner's claims if such claims are supported by medical records and/or opinion.

In this case, the undersigned finds that petitioner's claims are supported by medical records. Specifically, when petitioner reported to orthopedist Dr. Tan on April 6, 2016, she reported that the date of injury was October 30, 2015 (the date of vaccination), and that she had pain immediately which progressively worsened. When

petitioner reported to nurse practitioner Reynolds on May 25, 2016, she reported that when the flu shot was given it felt like something tore in her arm. In addition, physician assistant Stone noted on June 9, 2016 that petitioner received the flu vaccine on October 30, 2015 and her arm had been painful since that time. The physical therapy initial evaluation and subsequent physical therapy records document the date of onset of petitioner's injury as October 30, 2015. Finally, the VAERS report dated March 22, 2016 documents an onset date of October 31, 2015.

These medical records support and substantiate petitioner's detailed testimony and affidavit describing the onset of her symptoms. Taken together, the medical records, hearing testimony, and affidavits demonstrate that petitioner experienced pain immediately following vaccination and attempted to self-treat with ice packs for several months. She considered seeing a doctor but delayed doing so because she was uncertain what kind of doctor she should see and hoped that the pain would go away on its own. The fact that her first attempt to take steps beyond self-treatment involved returning to the pharmacy where she received the vaccine bolsters her explanation that she did not know what kind of doctor to see or where to seek help. The undersigned found petitioner to be a credible witness and finds her testimony and affidavit to be consistent with the medical records. Thus, the undersigned's finding that the preponderance of the evidence demonstrates that the onset of petitioner's injury occurred within 48 hours of vaccination is consistent with § 13(a)(1).

Furthermore, respondent's suggestion that petitioner must produce a medical opinion demonstrating a link between her vaccination and injury is not applicable in the context of this case. Because this case meets the requirements of a Table injury, causation is presumed and petitioner need not provide a medical opinion to establish causation. Therefore, the undersigned determines that respondent's objections are without merit.

V. Conclusion

In light of all of the above, and in view of the submitted evidence, including the medical records, affidavits, credible witness testimony, and fact ruling, the undersigned finds that petitioner is entitled to compensation under the Vaccine Act.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master